DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2007

Intelligent Hearing Systems
% Mr. Edward Miskiel, Ph.D
President & CEO
6860 SW 81st Street
Miami, Florida 33143

RE: K070608
Trade/Device Name: SmartEP M010000
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ, GWF, GWE, ETN
Dated: June 28, 2007
Received: June 29, 2007

Dear Dr. Miskiel:

This letter corrects our substantially equivalent letter of July 18, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K070608

Device Name: SmartEP (with Additional/Expanded Indications for Somatosensory Evoked Potential Testing, Visual Evoked Potential Testing, & Nerve Stimulation/Monitoring)

Indications for Use:

SmartEP is an evoked response testing and diagnostic device, that is capable of eliciting, acquiring, and measuring auditory, somatosensory, and visual evoked potential data, as well as providing nerve stimulation and monitoring.

The intended use of the SmartEP device is to objectively record evoked responses from patients of all ages upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory, visual) and in surgical procedures for inter-operative nerve monitoring.

The SmartEP system is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's, EP technologist's, surgeon's, or physician's office, operating room, or other appropriate setting.

The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and personal eartip, or earcup) and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for somatosensory evoked potential (SEP) testing are the patient's upper/lower limbs and head (with the contact object being two metal prongs or skin-surface electrodes connected to a constant-current stimulator probe) and to the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for visual evoked potential (VEP) testing are the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The possible anatomical sites of contact for nerve stimulation and monitoring testing are the patient's nerve tissue (with the contact object being sterile monopolar or bipolar nerve stimulator probe tips), the patient's tympanic membrane and cochlear promontory (with the contact object being a sterile stimulation needle electrode), and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070608

K070608

INTELLIGENT HEARING SYSTEMS

510(k) Summary

JUL 18 2007

Prepared By:	Intelligent Hearing Systems 6860 SW 81st Street Miami, FL 33143
Telephone:	(305) 668-6102
FAX:	(305) 668-6103
Contact Person:	Edward Miskiel
Date Summary prepared:	February 26, 2007
Name of the Device:	SmartEP (with Additional/Expanded Indications for Somatosensory Evoked Potential, Visual Evoked Potential, & Nerve Stimulation/Monitoring Testing)
Common Name:	Evoked Response System, Nerve Stimulator/Monitor
Classification Name:	Electrical Evoked Response Stimulator (per CFR 882.1870) Photic Evoked Response Stimulator (per CFR 882.1890) Nerve Stimulator/Monitor (per CFR 874.1820) Auditory Evoked Response Stimulator (per CFR 882.1900)
Predicate Device(s):	IHS *SmartEP* (K904926), Nicolet *Viking II* (K890495), Medtronic XOMED *NIM-Response* (K982595)
Device Description:	SmartEP is an evoked response system that is capable of eliciting, acquiring, and measuring auditory, somatosensory, and visual evoked potential data, as well as providing nerve stimulation/monitoring. The feature modifications described in this 510(k) are to incorporate additional/expanded indications to the SmartEP device for somatosensory evoked potential, visual evoked potential, and nerve stimulation testing to the previously FDA cleared indications for auditory evoked potential testing. Specifically, additional hardware and software features have been added to the original SmartEP device system to objectively acquire somatosensory/visual evoked potentials upon the presentation of a somatosensory/visual stimulus, and to provide nerve stimulation/monitoring functionality.
Intended Use:	The SmartEP device is intended to be used as a diagnostic aid and adjunctive tool in sensory related disorders and nerve stimulation/monitoring on patients of all ages. This is the **same intended use** as that of the predicate device(s).

Technological Characteristics:

The Intelligent Hearing Systems (IHS) family of products is intended to be used for recording and analysis of human physiological data for the purpose of diagnosis, screening, and treatment of sensory disorders and nerve monitoring.

Evoked response systems provide a means to elicit and acquire signals evoked in response to appropriate stimuli, and can be used for different kinds of tests: Auditory evoked potentials (AEP), somatosensory evoked potentials (SEP), visual evoked potentials (VEP), nerve stimulation/monitoring, cochlear promontory stimulation (transtympanic eABR), etc. These testing variations are called "modalities", and each modality has its own unique hardware/software requirements.

The feature modifications described in this 510(k) are to incorporate additional/expanded indications to the SmartEP device for SEP, VEP, and Nerve Stimulation/Monitoring testing to the previously FDA cleared indications for AEP testing (refer to FDA 510(k) #K904926). Specifically, additional hardware and software features have been added to the original SmartEP device system to objectively acquire somatosensory/visual evoked potentials upon the presentation of a somatosensory/visual stimulus, as well as to provide nerve stimulation and monitoring functionality.

SEP testing is performed by providing skin-surface (cutaneous) electrical stimulation to a patient's upper and lower limbs. A somatosensory stimulus (constant-current pulses, etc.) is presented to the subject's skin through the use of an SEP electrical stimulator probe which delivers the constant-current electrical stimulus through two metal prongs or skin-surface electrode connections. As in the case of AEP testing, the EEG response from the brain is recorded through the use of scalp electrodes placed on the patient, amplified/filtered, digitized, and averaged with multiple responses to obtain a final evoked response signal. SEP testing is useful to determine the integrity of the somatosensory pathways and how well the nerves that connect to the spinal cord are able to send and receive sensory information (such as pain, temperature, and touch), as well as to help diagnose the nature of any possible sensory impairment. The anatomical sites of contact for SEP testing are the patient's upper/lower limbs and head (with the contact object being two metal prongs or skin-surface electrodes connected to a constant-current stimulator probe) and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

VEP testing is performed by providing photic light stimulation to a patient's eyes. A visual stimulus (checker-board light patterns, light bars, etc.) is presented to the subject through the use of a visual stimulator light (or LED) array or monitor which delivers visual patterns covering a particular area of the field of view. As in the case of AEP testing, the EEG response from the brain is recorded through the use of scalp electrodes placed on the patient, amplified/filtered, digitized, and averaged with multiple responses to obtain a final evoked response signal. VEP testing is useful to determine the integrity of the visual pathways as well as to help diagnose the nature of any possible sensory impairment. VEP testing can help provide valuable diagnostic information about conditions such as optic neuritis, optic tumors, retinal disorders, and demyelineating diseases such as multiple sclerosis. The anatomical sites of contact for VEP testing are the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

Nerve Stimulation and Monitoring testing is performed by providing low-current electrical stimulation to a patient's nerve tissue during intra-operative/surgical procedures performed by a qualified surgeon. A low-current stimulus (constant-current pulses, etc.) is presented to the subject through the use of a sterile nerve stimulator probe (monopolar or bipolar) or needle electrode which delivers the constant-current electrical stimulus directly to the exposed tissue. The evoked nerve response is recorded through the use of various types of electrodes (sub-dermal, needle electrodes, etc.), amplified/filtered, and digitized (with possible use of averaging) to obtain an evoked response signal. Nerve Stimulation and Monitoring

testing is useful for nerve localization and integrity determination, intra-operative nerve monitoring during surgical procedures (facial, intra-cranial, peripheral, spinal, cochlear, etc.), direct stimulation for evoked responses (EP, EMG), and cochlear promontory stimulation (transtympanic eABR). The possible anatomical sites of contact for Nerve Stimulation and Monitoring testing are the patient's nerve tissue (with the contact object being sterile monopolar or bipolar nerve stimulator probe tips), the patient's tympanic membrane and cochlear promontory (with the contact object being a sterile stimulation needle electrode), and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The modifications associated with this new SmartEP modified device only affect the operation of the SEP, VEP, and nerve stimulation/monitoring hardware and software functionality. There are no changes to any part of the AEP functionality. The modified SmartEP device is identical to the original SmartEP device in its intended use and methodologies for AEP testing, which have not changed as a result of modifications to the general or electrical specifications of the device, except with additional indications and capability for somatosensory evoked potential, visual evoked potential, and nerve stimulation/monitoring testing. Thus, the modified SmartEP device can be used to perform the same tests provided by the listed original SmartEP device (i.e., AEP testing), as well as SEP, VEP, and nerve stimulation/monitoring testing.

The original SmartEP device (refer to FDA K904926) consists of the Universal Smart Box (the main hardware receiver unit containing electronic hardware) and external medical grade power supply, power cable, Opti-Amp bio-amplifier (refer to FDA K914876 and K052060), electrodes and leads, sound transducers, Universal Serial Bus cable, a laptop or desktop computer with a Universal Serial Bus port and Windows (2000, XP, Vista) operating system, along with SmartEP software.

For SEP testing, unlike the original SmartEP device, the modified SmartEP system also requires a separate SEP Electrical Stimulation Box and SEP Electrical Stimulator Probe to deliver a constant current electrical stimulus (through two metal prongs or skin-surface electrode connections) to the patient to elicit an evoked response. The metal prongs of the SEP Electrical Stimulator Probe are made of biocompatible Type-302 stainless steel, which meets the ISO-10993 standard. This commercially available grade of steel is commonly used for non-implant medical devices and dental appliances/prosthesis. The SEP Electrical Stimulation Box/Probe is powered by a medical grade power supply, and the patient is afforded protection and isolation via an isolation transformer (rated up to 3500 volts DC, 10 TeraOhms). In addition, control hardware and software is used to limit the current stimulation to 0-100mA into a load less than or equal to 4000 Ohms (0-400V).

For VEP testing, unlike the original SmartEP device, the modified SmartEP system also requires a separate VEP Visual Stimulation Box with stimulator LED light array to deliver visual patterns to the patient to elicit an evoked response. In this case, there is no added electrical patient contact. The type of LEDs used for stimulation are commercially available, low-intensity, diffuse, red LEDs with a peak wavelength of 625 nm. The illumination provided by these LEDs is of an eye safe intensity and wavelength according to the FDA/CDRH 21 CFR 1040 Performance Standard for Light-Emitting Products. Considering the maximum radiant output condition with all of the LEDs on simultaneously, the system provides an average maximum accessible emission intensity level of approximately 0.43 microWatts at a distance of 30 cm (12 inches) from the test subject. Due to the narrowband characteristics of the LEDs, there is no significant emission of energy in the infrared (IR) or ultraviolet (UV) region of the spectrum, and therefore no concern about this type of exposure.

For Nerve Stimulation and Monitoring testing, unlike the original SmartEP device, the modified SmartEP system also requires a separate Low-Current Stimulation Box to deliver a constant low-current electrical stimulus to the patient's exposed tissue to elicit an evoked nerve response. A separate nerve stimulator probe (monopolar or bipolar) or needle electrode which connects to the Low-Current Stimulator unit is

also required to provide direct stimulation to the patient, and is provided by an outside vendor pre-packaged and sterile. The Low-Current Stimulation Box is powered by a 9V battery, and the patient is afforded additional protection and isolation via an isolation amplifier. In addition, control hardware/software is used to limit the current stimulation to 0-5mA into a load less than or equal to 1500 Ohms (0-10V), and the output channels are capacitively-coupled to prevent the unintended accumulation of direct current (DC) charge.

Figures E-1 and E-2 show simplified block diagrams for the original SmartEP system and the modified SmartEP system with SEP, VEP, and Nerve Stimulator/Monitoring testing functionality.

Safety and Effectiveness:

The modified SmartEP device with SEP, VEP, Nerve Stimulation/Monitoring testing functionality utilizes the same design principles, circuit designs, and operating principles as are used in the original SmartEP device. All of the modifications to the SmartEP device were designed in accordance with procedures that meet FDA QSR Design Control and ISO-13485:2003 specifications.

The same Hazard/Risk Analysis was performed for the modified SmartEP device using the same Fault Tree Analysis (FTA) approaches as in the original device. Also, the same validation, verification, and testing techniques for both hardware and software were performed for the modified SmartEP device.

The Class I Accessible Emission safety criteria outlined in the FDA/CDRH 21 CFR 1040 Performance Standard for Light-Emitting Products were followed in terms of the peak wavelength, exposure duration, and radiant intensity level of the light stimulus used for VEP testing. The light output of the device is of an eye safe intensity and wavelength, and meets Class I light product specifications which are not considered to be hazardous.

The safe electrical design criteria outlined in the FDA Guidance Document for Evoked Response Stimulators were followed in terms of isolation, leakage current, and applied current specifications (i.e., pulse width, amplitude, and direct-current decoupling). The patient-connection hardware is basically the same as the original device. There are no newly-introduced hardware related methods by which the patient can be harmed or injured through use of the device. The same patient interface/isolation methods are used.

The modified SmartEP device will be evaluated and certified for both electromagnetic compatibility and electrical safety by a certified National Recognized Test Laboratory (NRTL), which will conduct the appropriate EMI/EMC testing for medical electrical equipment, to elements of the requirements of:

- EN60601-1:1990: "*Medical Electrical Equipment, Part 1: General Requirements for Safety.*"
- EN60601-1-2:2001: *"Medical Electrical Equipment, Part 1: General Requirements for Safety.2.Collateral Standard: Electromagnetic Compatibility – Requirements and Tests"*
- EN55011:1998: *"Industrial, Scientific, & Medical (ISM) Radio-Frequency Equipment – Radio Disturbances Characteristics – Limits & Methods of Measurements"*
- EN61000-3-2:1995: *"Electromagnetic Compatibility (EMC) – Part 3-2:Limits for Harmonic Current Emissions"*
- EN61000-3-3:1995: *"Electromagnetic Compatibility (EMC) Part 3-3: Limits of Voltage Fluctuations and Flicker in Low-Voltage Supply Systems for Equipment with Rated Current up to 16 A"*

Original SmartEP System Block Diagram

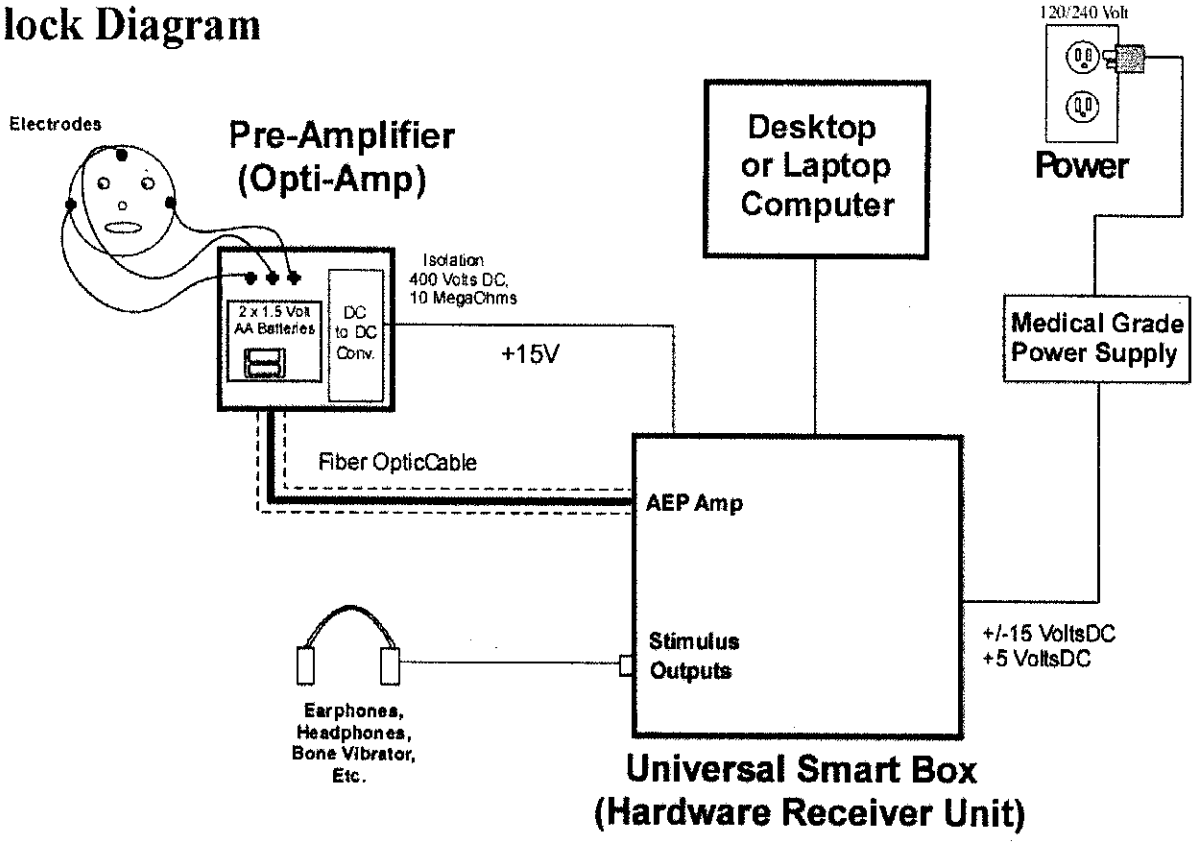

Figure E-1: Simplified block diagram of the original SmartEP system.

SmartEP System with SEP, VEP, & Low-Current Stimulator Block Diagram

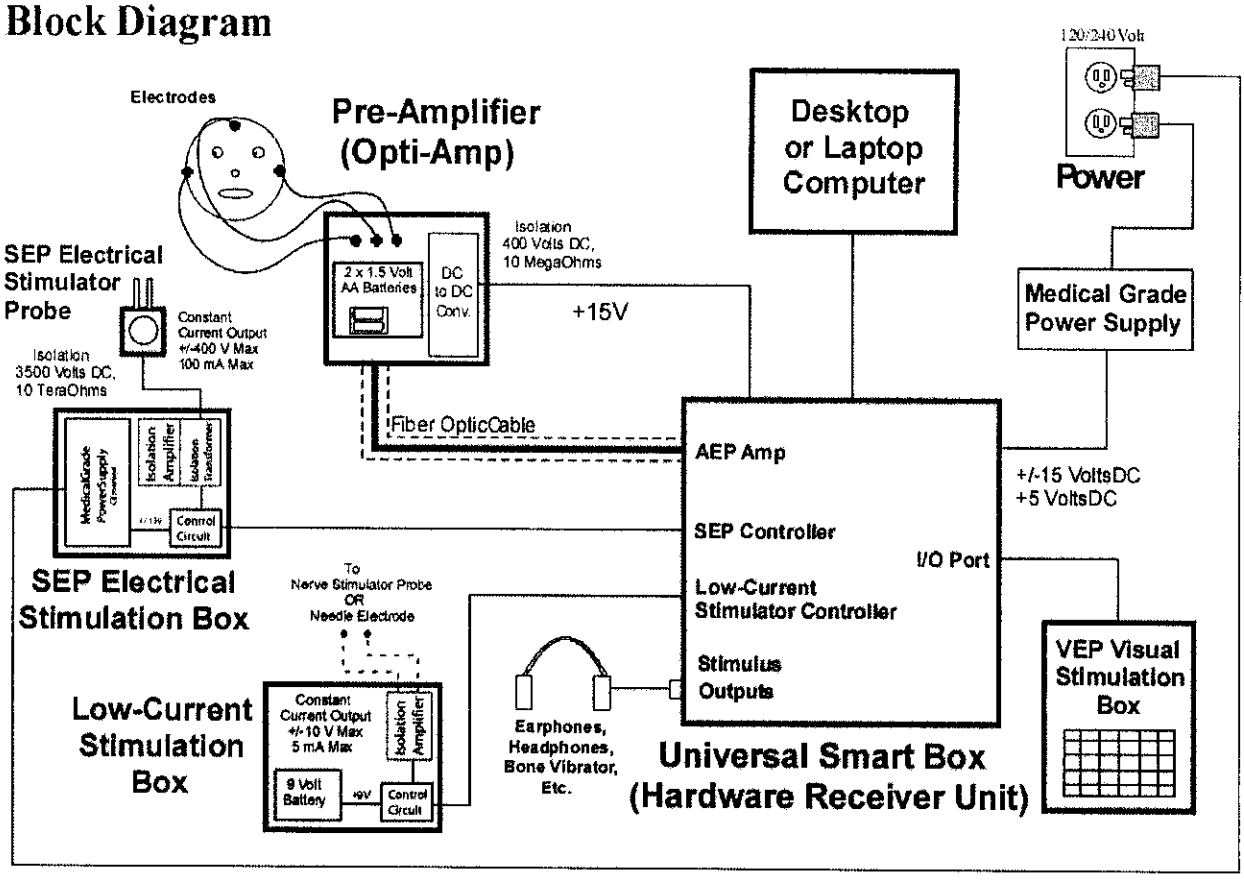

Figure E-2: Simplified block diagram of modified SmartEP system with SEP, VEP, & Nerve Stimulation/Monitoring testing functionality. This system uses an SEP Electrical Stimulation Box connected to an SEP Electrical Stimulator Probe unit (for SEP testing), a VEP Visual Stimulation Box unit (for VEP testing), and a Low-Current Stimulation Box unit (for Nerve Stimulation/Monitoring, transtympanic eABR testing). The SEP Electrical Stimulation Box/Probe is powered by a medical grade power supply, and the patient is afforded protection via an isolation transformer (rated up to 3500 volts DC, 10 TeraOhms). In addition, control hardware/software is used to limit the current stimulation to 0-100mA into a load less than or equal to 4000 Ohms (0-400V). The Low-Current Stimulation Box is powered by a 9 volt battery, and the patient is afforded additional protection via an isolation amplifier. In addition, control hardware/software is used to limit the current stimulation to 0-5mA into a load less than or equal to 1500 Ohms (0-10V), and the output channels are capacitively-coupled to prevent the unintended accumulation of direct current (DC) charge. The nerve stimulator probe (monopolar or bipolar) or needle electrode, which connects to the Low-Current Stimulator unit to stimulate the patient, is provided by an outside vendor pre-packaged and sterile.

Substantial Equivalence Based on Assessment of Performance Data:

The modifications described in this 510(k) are only concerned with the Somatosensory Evoked Potential (SEP), Visual Evoked Potential (VEP), and Nerve Stimulation/Monitoring testing aspects of the modified SmartEP device. The auditory evoked potential (AEP) testing aspects have already been previously submitted and cleared by the FDA (refer to FDA 510(k) #K904926).

With respect to SEP and VEP testing, the modified SmartEP device with SEP and VEP functionality is substantially equivalent to the *Nicolet Viking II* somatosensory electrical stimulator and visual stimulator device marketed by Nicolet Biomedical with FDA 510(k) clearance number K890495. Comparisons of general and performance specification parameters are given in Table E-1.

With respect to Nerve Stimulation/Monitoring testing, the modified SmartEP device with Nerve Stimulation/Monitoring functionality is substantially equivalent to the *NIM-Repsonse* nerve integrity monitor device marketed by Medtronic XOMED with FDA 510(k) clearance number K982595. Comparisons of general and performance specification parameters are given in Table E-2.

SPECIFICATIONS

Parameter	**Predicate Device** *Nicolet Viking II (K890495)*	**Device Under Current 510(k) Review** *SmartEP (SEP & VEP)*
Intended Use	SEP: Stimulate, record, and process somatosensory evoked potentials VEP: Stimulate, record, and process visual evoked potentials	Same
Indications for Use	The recording and analysis of physiological data necessary for the diagnosis of somatosensory and visual related disorders.	Same
Target Population	All Ages	Same
Design	External box housing circuitry connected to CPU via a RS232 connection	External box housing circuitry connected to personal computer via a USB connection
Materials	Assorted electrical components, circuit boards, SEP electrical stimulation box, SEP electrical stimulator probe, video monitor, and electrodes	Assorted electrical components, circuit boards, SEP electrical stimulation box, SEP electrical stimulator probe, visual stimulation LED array, and electrodes
Sterility	None Required	Same
Biocompatibility	Completely Biocompatible	Same

Anatomical Sites	SEP: Upper/lower limbs and head VEP: Scalp	Same
Energy Delivery	SEP: Stimulation of upper or lower limbs with surface electrical signals VEP: Stimulation of eyes with visual light patterns	Same
Where Used	Clinical Setting	Same
Safety	Conforms to UL544 & IEC 60601-1	Meets EN 60601-1
Patient Isolation	Type BF (IEC 60601-1) (*for data*), Fiber Optic Signal Link	Type BF (IEC 60601-1) (*for data*), Fiber Optic Signal Link (*for amp*), Medical-grade power supplies, 4000Vdc, 10 MegaOhms (*for power*) 3500Vdc, 10 TeraOhms (*for probe*) Isolation transformers, Isolation amplifiers
Somatosensory Stimuli		
Types	Constant Current or Voltage	Constant Current
Mode	User selectable: Single, Dual, or Stimulus Train	Same
Shape	Mono or Biphasic pulses	Same
Repetition Rate	0.1 - 100 Hz	Same
Phase/Polarity	Positive or Negative	Positive, Negative, or Alternating
Duration /Pulse Width	10 - 1000 microseconds	10 - 600 microseconds (Total duration of all components may only add up to 1 millisecond)
Stimulus Intensity Levels	Current: 0 - 100 mA, Voltage: 0 - 400V (Continuous adjustable level with user selectable maximum range into a 4000 Ohms load)	Current: 0 - 100 mA (400 Volt maximum) (Continuous adjustable level with user selectable maximum range into a 4000 Ohms load)
Biocompatibility	None Specified	SEP Stimulator Probe metal prongs made of Type-302 stainless steel, which meets ISO-10993 standard

Visual Stimuli		
Output Illumination	None Specified	Red LED Light (Class I AEL Level) Peak Wavelength: 625 nm Maximum Accessible Power: < 0.43 microWatts (at a distance of 30cm (12 inches))
Pattern Types	Checkerboard, Horizontal Bars, Vertical Bars	Same
Pattern Fields	User selectable: Full field, Half field, and Quarter-field	User selectable: Full field, Half field, Quarter-field, and Displacements
Pattern Presentation	User selectable: Pattern Reversal and Pattern Flash	User selectable: Pattern Reversal, Pattern Flash, and Pattern Shift
Repetition Rate	0.1 - 30 Hz	0.1 - 100 Hz

Table E-1: General and performance specifications of predicate device & current device under 510(k) review for Somatosensory & Visual Evoked Potential Testing.

Parameter	Predicate Device *NIM-Response (K982595)*	Device Under Current 510(k) Review *SmartEP (Nerve Stimulation)*
Intended Use	Stimulate, record, and process evoked nerve responses	Same
Indications for Use	Nerve stimulation & monitoring	Same
Target Population	All Ages	Same
Design	Main hardware receiver/monitor unit with touch-screen display (to control test setup, monitoring, and storage), which connects to a separate isolated Patient Interface Unit (including input amplifier channels & output stimulator channels) for stimulation & acquisition	External hardware receiver unit which connects to a separate isolated battery-powered Low-Current Stimulation Box for stimulation, a separate isolated bio-amplifier unit for acquisition, and a personal computer (via a USB connection) for test setup, processing, monitoring, and storage through software
Sterility	Requires use of sterile nerve stimulator probe (monopolar or bipolar) and sterile subdermal/needle electrodes for patient contact	Same
Biocompatibility	Completely Biocompatible	Same
Anatomical Sites	Patient's exposed nerve/soft tissue, intramuscular, subdermal; skin, scalp, and possibly other body sites	Same
Energy Delivery	Stimulation of exposed nerve tissue with low-current electrical signals	Same
Where Used	Intra-Operative/Surgical Setting	Same
Safety	Complies with IEC 60601-1, UL2601-1, CSA22.2 No.601, AS3200	Complies with EN 60601-1
Patient Isolation	Type BF (IEC/EN 60601-1) , 4000Vpp 60Hz dielectric withstand from Line Connections to signal ground (*for power*), <u>Main Unit Fuse</u>: TypeF 250V, 2- 4 A 1000VRMS 60Hz, 2MegaOhms (*for amplifier*), <u>Stimulator Fuse</u>: TypeF 250V, 32mA	Type BF (IEC 60601-1) 4000Vdc, 10 MegaOhms (*for power*) Medical-grade power supply Fiber Optic Signal Link (*for amplifier*), <u>Stimulator Fuse</u>: 15.6 mA (1500ohm load impedance), Battery-powered stimulator, Isolation amplifier

Nerve Stimuli		
Transducers	Nerve stimulator probe (monopolar or bipolar), Needle Electrodes	Same
Types	Constant Current, Pulsed	Same
Mode	Stimulus Train	User selectable: Single, Dual, or Stimulus Train
Shape	Monophasic pulses	Mono- or Biphasic pulses
Repetition Rate	1, 4, 7, & 10 Hz	1 - 10 Hz
Phase/Polarity	Negative	Positive, Negative, or Alternating
Duration /Pulse Width	50, 100, & 250 microseconds	10 - 200 microseconds
Stimulus Intensity Levels	Current: 0 - 3 mA (12 Volt maximum)	Current: 0 - 5 mA (10 Volt maximum)
Biocompatibility	Nerve stimulator probe and/or subdemal/needle electrodes completely biocompatible meeting ISO-10993 standard for soft tissue contact	Same
Sterility	Nerve stimulator probe and/or subdermal/needle electrodes provided pre-packaged and sterile	Same

Table E-2: General and performance specifications of predicate device & current device under 510(k) review for Nerve Stimulation/Monitoring Testing.

Product Labeling:

In this 510(k) application there are changes in the intended use, advertisements, and directions for use due to the type of modifications to the original SmartEP device marketed by Intelligent Hearing Systems with FDA 510(k) clearance numbers K904926. These changes only deal with the new Somatosensory Evoked Potential (SEP), Visual Evoked Potential (VEP), and Nerve Stimulation/Monitoring testing aspects of the device. The original Auditory Evoked Potential (AEP) testing aspects have not been changed.

The only changes in product labeling between the predicate device and the device under current 510(k) review are in the additional electrical safety labels (which include the reference model numbers and the power specifications) for the SEP Electrical Stimulation Box, SEP Electrical Stimulator Probe, VEP Visual Stimulation Box, and Low-Current Stimulation Box. These changes are a result of the modifications mentioned in this 510(k). The electrical safety labels for the Universal Smart Box (USB), SEP Electrical Stimulation Box, SEP Electrical Stimulator Probe, VEP Visual Stimulation Box, and Low-Current Stimulation Box are shown in the figure below. Note that power is supplied to the SEP Electrical Stimulator Probe through the SEP Electrical Stimulation Box, and power is supplied to the VEP Visual Stimulation Box through the Universal Smart Box.

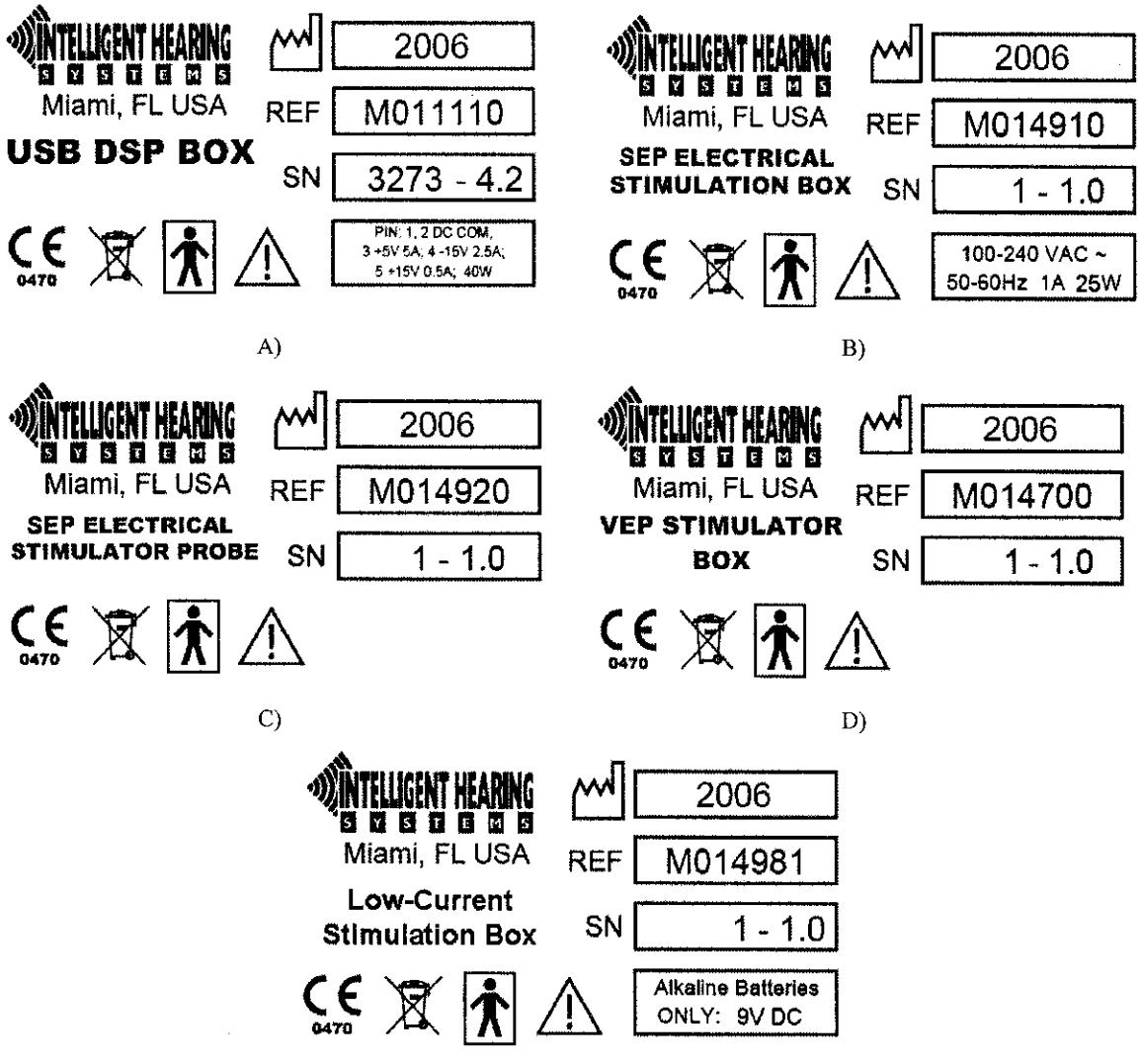

Figure E-3: Electrical safety labels for the A) Universal Smart Box (USB), B) SEP Electrical Stimulation Box, C) SEP Electrical Stimulator Probe, D) VEP Visual Stimulation Box, and E) Low-Current Stimulation Box.

Declaration of Conformity:

As required by our risk analysis, all verification and validation activities have been performed for the modified SmartEP device by designated individuals at Intelligent Hearing Systems. The results have demonstrated that all predetermined acceptance criteria have been met, in accordance with our ISO-13485 quality system. All records, including Device Master Records and Design History Files, are available for review upon request.

Edward Miskiel, Ph.D.
President & CEO

2/26/07
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2007

Intelligent Hearing Systems
% Mr. Edward Miskiel, Ph.D
President & CEO
6860 SW 81st Street
Miami, Florida 33143

RE: K070608
Trade/Device Name: SmartEP M010000
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: June 28, 2007
Received: June 29, 2007

Dear Dr. Miskiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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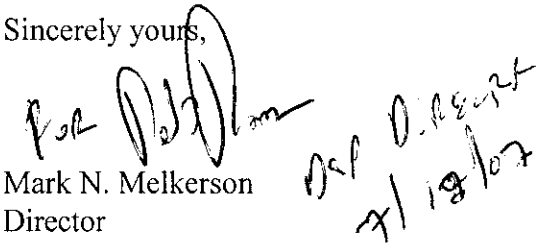
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address: http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K070608

Device Name: **SmartEP** (with Additional/Expanded Indications for Somatosensory Evoked Potential Testing, Visual Evoked Potential Testing, & Nerve Stimulation/Monitoring)

Indications for Use:

SmartEP is an evoked response testing and diagnostic device, that is capable of eliciting, acquiring, and measuring auditory, somatosensory, and visual evoked potential data, as well as providing nerve stimulation and monitoring.

The intended use of the SmartEP device is to objectively record evoked responses from patients of all ages upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory, visual) and in surgical procedures for inter-operative nerve monitoring.

The SmartEP system is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's, EP technologist's, surgeon's, or physician's office, operating room, or other appropriate setting.

The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and personal eartip, or earcup) and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for somatosensory evoked potential (SEP) testing are the patient's upper/lower limbs and head (with the contact object being two metal prongs or skin-surface electrodes connected to a constant-current stimulator probe) and to the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for visual evoked potential (VEP) testing are the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

The possible anatomical sites of contact for nerve stimulation and monitoring testing are the patient's nerve tissue (with the contact object being sterile monopolar or bipolar nerve stimulator probe tips), the patient's tympanic membrane and cochlear promontory (with the contact object being a sterile stimulation needle electrode), and the patient's scalp and possibly other body sites (with the contact object being electrodes that are capable of measuring bio-potentials).

Prescription Use __X__ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070608